IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH and BIOGEN MA INC., Plaintiffs, v. AMNEAL PHARMACEUTICALS LLC, et al., Defendants.	)	Civil Action No. 17-823-MN (Cons.)

DEFENDANTS' SUPPLEMENTAL POST-TRIAL BRIEF ON THE INVALIDITY OF THE '514 PATENT

TABLE OF CONTENT

Page

I. INTRODUCTION....1

II. BACKGROUND....1

III. ARGUMENT....2

A. Biogen Is Collaterally Estopped From Contesting The Mylan Court's Decision Finding The '514 Patent Invalid For Lack Of Written Description....2

B. Alternatively, Defendants Ask That The Court Issue A Ruling On The Merits That The '514 Patent Is Invalid For At Least Lack Of Written Description....5

IV. CONCLUSION....5

TABLE OF AUTHORITIES

Page(s)

Cases

Biogen International GmbH v. Mylan Pharmaceuticals, Inc.,
No. 1:17CV116, DI 400 (N.D. W. Va. June 18, 2018) 1, 2

Blonder–Tongue Laboratories, Inc. v. University of Illinois Foundation,
402 U.S. 313 (1971) 3, 4

Blumcraft v. Kawneer Co. Inc.,
482 F.2d 542 (5th Cir. 1973) 5

Galderma Labs. Inc. v. Amneal Pharm., LLC,
921 F. Supp. 2d 278 (D. Del. 2012) 3

Kaiser Indus. Corp. v. Jones & Laughlin Steel Corp.,
515 F.2d 964 (3d Cir. 1975) 3

Mendenhall v. Barber-Greene Co.,
26 F.3d 1573 (Fed. Cir. 1994) 3, 4

Mississippi Chemical Corp. v. Swift Agr. Chemicals Corp.,
717 F.2d 1374 (Fed. Cir. 1983) 5

Nuvo Pharms. v. Dr. Reddy's Labs. Inc.,
923 F.3d 1368 (Fed. Cir. 2019) 2

Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.,
170 F.3d 1373 (Fed. Cir. 1999) 3, 4

Soverain Software LLC v. Victoria's Secret Direct Brand Mgmnt, LLC,
778 F.3d 1311 (Fed. Cir. 2015) 3

Stevenson v. Sears, Roebuck & Co.,
713 F.2d 705 (Fed. Cir. 1983) 5

U.S. Ethernet Innovations, LLC v. Texas Instruments Inc.,
645 F. App'x 1026 (2016) 4

I. INTRODUCTION

Defendants in this consolidated action respectfully request that the Court enter a judgment holding claims 1-4, 6, 8-13 and 15-16 of U.S. Patent No. 8,399,514 (the "'514 patent") invalid due to collateral estoppel based on the final judgment in *Biogen International GmBH v. Mylan Pharmaceuticals, Inc.*, No. 1:17 Civ. 116, D.I. 400 (N.D. W. Va. June 18, 2020) or, in the alternative, conclude the asserted claims of the '514 patent are invalid on the merits.[1]

II. BACKGROUND

In December 2019, this Court held a bench trial regarding the validity of the '514 patent in which Defendants presented, *inter alia*, a written description invalidity defense. In February 2020, Biogen went to trial against Mylan in the Northern District of West Virginia, where it litigated the same written description invalidity defense presented at trial before this Court.

Based on the same evidence and arguments Biogen presented to this Court, the court in the Mylan case issued a decision on June 18, 2020, finding the very same claims of the '514 patent asserted in this case to be invalid for lack of written description. Final judgment was entered in the Mylan case on June 22, 2020. (Ex. 1, *Biogen v. Mylan*, D.I. 413.)

In a thorough and well-reasoned opinion, the Mylan court examined the specification and found that the only relevant method (i.e., Method 4) "makes no mention of treating MS with a 480mg/day dose of DMF (BID)." (D.I. 376-1 at 26). Indeed, "Method 4 broadly describes treating neurological diseases with a therapeutically effective amount of DMF; MS is merely one such disease 'among a slew of competing possibilities.'" (*Id.* at 27). "[T]here are no 'blaze marks' in Method 4 that would lead a POSA specifically to MS." (*Id.* at 29). The Mylan court rejected

[1] Defendants presented defenses of invalidity based on lack of written description, lack of enablement, improper inventorship, obviousness, and anticipation, any one of which would provide a proper basis for the Court to hold the patent invalid.

Biogen's argument that Method 4 "'link[s]' a therapeutically effective amount of DMF to a dose of 480 mg/day" based on the sole passage in the patent that mentions 480 mg/day as part of a range of doses, because nothing in that passage "ties an effective dose of DMF specifically to the treatment of MS." (*Id.*). The Mylan court relied on testimony elicited in this case to conclude: "[g]iven the emphasis on 720 mg/day of DMF, nothing in this passage teaches a POSA that a 480 mg/day dose of DMF (BID) is therapeutically effective for treating MS." (*Id.* at 31-33 (relying on Dr. Wynn's testimony from this case)).

The Mylan court also found it persuasive that the published Phase II clinical trials pointed to the 720 mg/day dose and suggested that lower doses were not effective (*id.* at 30-31), rejected Biogen's argument that Example 3 provides written description support (*id.* at 33-38), and concluded that—in contrast to Biogen's abandoned application specifically directed to dosing and containing much more than just a mention of 480 mg/day (*id.* at 38-42)— the '514 patent specification contained inadequate written description. In sum, the court found that "[t]his case bears a striking resemblance to *Nuvo Pharmaceuticals*," in which the Federal Circuit found lack of written description for a method of treatment that no POSA would have believed would work at the time of filing. (*Id.* at 42-44 (citing *Nuvo Pharms. v. Dr. Reddy's Labs. Inc.,* 923 F.3d 1368 (Fed. Cir. 2019)). All of these arguments were raised in this case as well (*see* D.I. 366 at 4-5, 8-11, 12-13), and the Mylan court's conclusion should apply equally here.

III. ARGUMENT

A. Biogen Is Collaterally Estopped from Contesting the Mylan Court's Decision Finding the '514 Patent Invalid for Lack of Written Description.

Biogen is collaterally estopped from asserting invalid claims 1-4, 6, 8-13, and 15-16 of the '514 patent against Defendants in this case. This Court should enter final judgment applying

collateral estoppel and allow Defendants to timely coordinate any appeal of this case with Mylan's appeal now pending before the Federal Circuit.

Collateral estoppel limits patent owners to "one full and fair opportunity for judicial resolution of the same [invalidity] issue." *Blonder–Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 328 (1971).[2] "[O]nce the claims of a patent are held invalid in a suit involving one alleged infringer, an unrelated party who is sued for infringement of those claims may reap the benefit of the invalidity decision under principles of collateral estoppel." *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1379 (Fed. Cir. 1999) (quoting *Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1577 (Fed. Cir. 1994)). The doctrine applies even when the previous case is on appeal and even after a trial on the merits has occurred. *Galderma Labs. Inc. v. Amneal Pharm., LLC*, 921 F. Supp. 2d 278, 281 (D. Del. 2012) (a judgment is final for purposes of collateral estoppel, even when the case is still on appeal); *Pharmacia*, 170 F.3d at 1381 (same); *Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1579 (Fed. Cir. 1994) ("[T]he defense of collateral estoppel based on a final judgment of patent invalidity in another suit can be timely made at any stage of the affected proceedings.").

Collateral estoppel, also known as issue preclusion, applies when "(1) the previous determination was necessary to the decision; (2) the identical issue was previously litigated; (3) the issue was actually decided on the merits and the decision was final and valid; and (4) the party being precluded from re-litigating the issue was adequately represented in the previous action." *Galderma*, 921 F. Supp. 2d at 280. All four of these elements have been met here.

[2] "We apply the law of the regional circuit to the general procedural question of whether issue preclusion applies. We apply this court's precedent to questions involving substantive issues of patent law, issues of issue preclusion that implicate substantive patent law issues, or issues of issue preclusion that implicate the scope of our own previous decisions." *Soverain Software LLC v. Victoria's Secret Direct Brand Mgmnt, LLC*, 778 F.3d 1311, 1314 (Fed. Cir. 2015).

Biogen cannot credibly dispute that all four determinative factors are satisfied. The Mylan court decided the identical issue of whether the '514 patent claims are invalid for lack of written description, a case dispositive ruling resulting in a final judgment. It is also beyond dispute that Biogen had a full and fair opportunity to litigate the issue in the Mylan case, with its same counsel confronting the same issue, using the same fact and expert witnesses, and making the same arguments presented here. The Mylan court's thorough and comprehensive opinion, addressing only written description, readily shows that it fully understood the subject matter and issues in the litigation. That is all that is required. *Pharmacia*, 170 F.3d at 1380 (observing that "a district court's inquiry into whether the plaintiff was afforded a full and fair opportunity to litigate is quite narrow and does not involve a judgment on the merits" and holding that the court's comprehensive opinion denying JMOL demonstrated full and fair opportunity).

Without any argument to make based on the four elements, Biogen is left to contend that the circumstances of this case are somehow different because the case has already proceeded through trial and there is less to be gained from an efficiency perspective.[3] The fact trial has occurred is irrelevant. *See U.S. Ethernet Innovations, LLC v. Texas Instruments Inc.*, 645 F. App'x 1026, 1027-28, 1030 (Fed. Cir. 2016) (upholding application of collateral estoppel of patent invalidity after jury verdict); *Mendenhall*, 26 F.3d at 1580 (same); *Eli Lilly & Co. v. Sicor Pharmaceuticals, Inc.*, 705 F. Supp. 2d 971, 991 (S.D. Ind. 2010) (applying collateral estoppel post-trial). *Blonder-Tongue* and its progeny "do[] not contemplate or sanction the determination, on a case-to-case basis, whether considerations of efficiency and economy warrant application of

[3] The parties conferred on the applicability of collateral estoppel. Biogen did not contend that any of the four factors were unsatisfied, and instead said its opposition is based on the equitable nature of collateral estoppel and the fact the parties have already conducted a trial. (Ex. 2, 6/29/2020 email). Despite Defendants requests, Biogen was unable to identify any cases in which a court declined to apply collateral estoppel for such reasons. (*Id.*).

collateral estoppel in a particular situation before the court." *Miss. Chemical Corp. v. Swift Agr. Chemicals Corp.*, 717 F.2d 1374, 1378 (Fed. Cir. 1983); *Kaiser Indus. Corp. v. Jones & Laughlin Steel Corp.*, 515 F.2d 964, 978 (3d Cir. 1975) (rejecting argument that "generalized concepts of justice and equity constitute an independent ground for denying an estoppel defense"). Rather, it operates to "prevent relitigation of patent validity once the patent has been held invalid in a case in which the patentee had a full and fair opportunity to litigate the issue." *Miss. Chemical Corp.*, 717 F.3d at 1378. There is no room for discretion: "***this defense must be accepted*** by a court unless the patentee demonstrates that he was denied a full and fair opportunity to litigate the validity" of the patent. *Stevenson v. Sears, Roebuck & Co.*, 713 F.2d 705, 709 (Fed. Cir. 1983) (emphasis added); *Blumcraft v. Kawneer Co. Inc.*, 482 F.2d 542, 547 (5th Cir. 1973) (same).

Because collateral estoppel applies here, the Court should issue a judgment in Defendants' favor, including the stayed defendants, that the asserted claims of the '514 patent are invalid.

B. Alternatively, Defendants Ask That The Court Issue A Ruling On The Merits That The '514 Patent Is Invalid For At Least Lack Of Written Description.

If this Court accepts Biogen's argument that collateral estoppel does not apply, the Court should find the asserted claims of the '514 patent invalid. In particular, for all the reasons set forth in Defendants' post-trial briefs and the Mylan court's comprehensive decision on written description, this Court should hold that the asserted claims of the '514 patent are invalid for at least lack of written description, or any of the remaining defenses presented by Defendants.

IV. CONCLUSION

For the foregoing reasons, Defendants respectfully contend that this Court must apply collateral estoppel and enter judgment of invalidity or, if the Court disagrees, issue an opinion that the asserted claims of the '514 patent are invalid for at least lack of written description.

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